

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

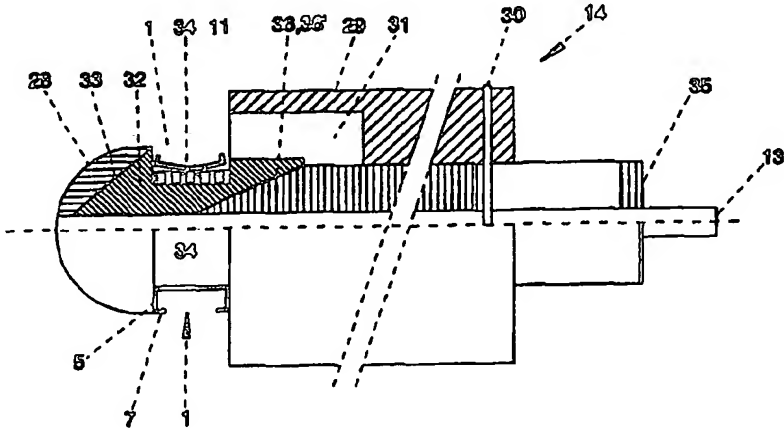
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/115, 17/064, 17/11	A1	(11) International Publication Number: WO 99/21491 (43) International Publication Date: 6 May 1999 (06.05.99)
<p>(21) International Application Number: PCT/NL98/00605</p> <p>(22) International Filing Date: 22 October 1998 (22.10.98)</p> <p>(30) Priority Data: 1007349 24 October 1997 (24.10.97) NL</p> <p>(71)(72) Applicants and Inventors: SUYKER, Wilhelmus, Josphe, Leonardus [NL/NL]; Zalmkolk 13, NL-8017 PB Zwolle (NL). SUYKER, Paulus, Thomas, Wilhelmus [NL/NL]; Singel 208 F, NL-1016 AA Amsterdam (NL).</p> <p>(74) Agent: METMAN, Karel, Johannes; De Vries & Metman, Gebouw Autumn, Overschiestraat 184 N, NL-1062 XK Amsterdam (NL).</p>	<p>(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, ES, FI, FI (Utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> <i>In English translation (filed in Dutch).</i></p>	
<p>(54) Title: MECHANICAL ANASTOMOSIS SYSTEM FOR HOLLOW STRUCTURES</p> <p>(57) Abstract</p> <p>A system for making anastomoses between hollow structures by mechanical means is provided with a device in the shape of an annular or tubular element comprising circumferentially provided means, such as pin-shaped elements, for joining the abutting walls of the hollow structures together. An applicator is intended for moving said annular or tubular element in position and activating the joining means thereof, so as to make the anastomosis. Possibly, intraluminal joining means can be inserted without using an annular or tubular element.</p> 		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

MECHANICAL ANASTOMOSIS SYSTEM FOR HOLLOW STRUCTURES

The present invention relates to a system for making anastomoses between hollow structures by mechanical means, and also to a device and an applicator for use therewith.

5 Such a system may for example be used when making a bypass past narrowings or occlusions of arteries caused by arteriosclerosis. There are now various possibilities of remedying such constrictions or occlusions.

10 If the constriction or occlusion takes place in a coronary artery, the least radical method is to dilate the constriction by means of a PTCA procedure (Percutaneous Transluminal Coronary Angioplasty), which may or may not be followed by the placing of an intraluminal stent. This is not always possible, however.

15 On the other hand, as already mentioned before, it is possible to make a bypass by means of surgery. To this end an artery (arteria mammaria interna) or a vein from the leg (vena saphena magna) may be used, for example. An anastomosis is thereby made in the coronary artery, distally
20 of the constriction or occlusion. The interconnection between the vessels is then manually sutured by means of 8 to 20 stitches. Said anastomosis may be a side-to-side or an end-to-side anastomosis. The natural origin of the arteria mammaria interna is usually preserved, so that such a bypass
25 will directly be functional. A bypass made of a vena saphena magna will have to be sutured separately in the aorta (the so-called proximal anastomosis). Due to the small diameter of coronary arteries (1 - 3 mm), it is generally decided to stop the heart in order to be able to carry out the
30 anastomosis precisely and safely. The blood circulation is kept going by a heart-lung machine during this time. Although this is a well-tried and reasonably safe method, it has certain drawbacks. Thus, the use of the heart-lung

machine has a number of side effects for the patient, as a result of which recovery following surgery takes more time. Moreover, the necessary disposables for the heart-lung machine are costly.

5 At present, techniques are available for a number of readily accessible coronary arteries to make manually sutured vascular connections to a beating, functioning heart. Generally, a device which more or less immobilizes a small area of the heart by mechanical means is used thereby.

10 The drawbacks of said method are the fact that only a limited number of places on the heart can be reached and the fact that part of the heart is temporarily anaemic, because it is necessary to stop the circulation through the blood vessel to be treated for 8 - 15 minutes.

15 The object of the present invention is to provide a system for making anastomoses between hollow structures by mechanical means, which will make it easier to make mechanical anastomoses.

 In order to accomplish that objective, the system

20 according to the invention is characterized by a device in the shape of an annular or tubular element comprising joining means provided circumferentially thereon for joining the abutting walls of the hollow structures together, as well as an applicator for moving said annular or tubular

25 element in position and activating the joining means thereof.

 The system according to the invention makes it possible to effect an anastomosis faster and more easily by placing an annular or tubular element comprising joining

30 means with the aid of said applicator, which joining means are also activated by said applicator, in such a manner that the anastomosis is made.

 The system according to the invention has a wide range of applications, due to the fast and accurate manner

35 of making an anastomosis. Thus, the following applications are conceivable:

- "port access surgery", such as laparoscopic or thoracoscopic vascular reconstructions;
- small, precise vascular connections to a moving organ, as in heart surgery; and
- 5 - vascular reconstructions wherein the circulation through the supplying vessel may only be shut off for a very short period of time, as in neurosurgery.

Of course, it is also possible to use the invention
10 to make anastomoses between other hollow structures.

The invention also comprises embodiments of devices and applicators for use in the above-described system for making anastomoses by mechanical means.

The device of the system according to the invention
15 can be used intraluminally as well as extraluminally, and it can be adapted both for side-to-side anastomoses and for end-to-side anastomoses. The joining means are preferably pin-shaped elements, whereby pairs of pin-shaped elements may be considered, which can function as staples, or
20 independently operating pin-shaped elements, which can be fixed to the vessel walls by being deflected. Preferably, the tubular or annular elements for intraluminal use can expand from a smaller starting diameter to a final joining diameter, whereby the joining means can be activated either
25 automatically upon expansion or individually. The elements may have a circular cross-section, but also an elliptical cross-section, for example, so that the resulting anastomosis will also have a circular or an elliptical cross-section.

30 The invention furthermore comprises a method for making intraluminal side-to-side or side-to-end anastomoses between hollow structures by mechanical means, which is characterized by providing an applicator and associated joining means for joining the abutting walls of the hollow
35 structures together, placing said joining means round the applicator, inserting said applicator and said joining means into one of said hollow structures to a location internally

of the abutting walls of the hollow structures, and activating said applicator, and thus passing said joining means through said abutting walls or clamping said joining means against said abutting walls for the purpose of keeping
5 said abutting walls in sealing contact with each other.

With this method, a number of loose staples may be used as the joining means.

The invention will be explained in more detail hereafter with reference to the drawings, which show
10 embodiments of the invention.

Fig. 1 is a perspective view of a first embodiment of the device for making anastomoses by mechanical means according to the invention, showing the starting position thereof.

15 Fig. 2 is a side view of the device according to Fig. 1.

Fig. 3 is an axial view of the device according to Fig. 1.

Fig. 4 is a perspective view of the device
20 corresponding with Fig. 1, wherein the device is shown in the joining position, however.

Figs. 5 and 6 are a side view and an axial view, respectively, of the device of Fig. 4.

Figs. 7 - 12 are views corresponding with Figs. 1 -
25 6 of a second embodiment of the device according to the invention.

Fig. 13 is a side view of an applicator for use with the device according to Figs. 7 - 12, showing the starting position thereof.

30 Fig. 14 is a perspective view of the applicator of Fig. 13, with the device according to Figs. 7 - 12, which is shown in the starting position thereof, in mounted position thereon.

Fig. 15 is a side view corresponding with Fig. 13,
35 wherein the applicator is shown in the joining position, however.

Figs. 16 - 21 are views corresponding with Figs. 1 - 6 of a third embodiment of the device according to the invention.

Figs. 22 - 24 are views corresponding with Figs. 13 - 15 of an applicator for use with the device according to Figs. 16 - 21.

Fig. 25 is a schematic side view, partially in sectional view, of an alternative applicator for use with the device according to Figs. 1 - 6 or 7 - 12.

Fig. 26 is a partial front view of the applicator of Fig. 25.

Fig. 27 is a view corresponding with Fig. 25, wherein the applicator is shown in the expanded position, however.

Figs. 28 - 30 are sectional views and elevational views respectively corresponding with Figs. 25 - 27 of a variant of an applicator for use with a device according to Figs. 16 - 21.

Figs. 31 - 33 are partially cut-away side views of another variant of the applicator, for example for use with a device according to Figs. 1 - 6 or 7 - 12, showing three different positions thereof.

Fig. 34 is a side view of a variant of the extendible arms of the applicator of Fig. 31.

Figs. 35, 36 are perspective views of the applicator of Fig. 31, showing the two extreme positions thereof.

Figs. 37, 38 and 39, 40 are side views and perspective views, respectively, of yet another variant of the applicator according to the invention for use with a device according to Figs. 1 - 6 or 7 - 12, for example, showing the two extreme positions thereof.

Fig. 41 is a highly schematic perspective view of blood vessels interconnected by side-to-side anastomose with loose staples.

Figs. 1 - 6 show a first embodiment of a device for making anastomoses between hollow structures, in particular arteries or veins, by mechanical means.

In the present case, the device is a one-piece
5 tubular or annular element 1, which is made of a biocompatible and plastically deformable material, for example a tantalum alloy or another material used in medical technology. Annular element 1 may be considered to be an assembly of two zigzag-like elongated elements 2 and 3 which
10 extend substantially in circumferential direction but not along the contour line, which elements are interconnected at the facing vertices, thus forming a ring of diamond-shaped structures 4. Present on the vertices of the zigzag-like elements 2, 3 that face away from each other are pin-shaped
15 elements 5, 6, which are provided with sharp tips 7 at their ends facing away from annular element 1, wherein the tips 7 of two associated pin-shaped elements 5, 6 forming a pair are directed towards each other. The pin-shaped elements may be straight, but also curved or angular, for example, thus
20 forming staples which are C-shaped, as it were, whilst the pin-shaped elements may also be shaped more like lips.

Since annular element 1 is formed from elongated elements 2, 3, whose length in circumferential direction is greater than that of annular element 1 in the position as
25 shown in Figs. 1 - 3, and since elements 2 and 3 are capable of deformation, it is possible to expand annular element 1 from the starting position as shown in Figs. 1 - 3 to a final position, or joining position, as shown in Figs. 4 - 6. In said joining position, annular element 1 has a
30 diameter which is associated with a diameter which is at most equal to the length of elongated elements 2, 3. It would also be possible, of course, to expand annular element 1 only to a smaller diameter.

As is apparent from a comparison between Figs. 4 -
35 6 and 1 - 3, the diamond-shaped structures 4 are deformed to a straighter shape, seen in circumferential direction, wherein the vertices comprising the pin-shaped elements 5, 6

have been moved closer together, such that the points 7 of pin-shaped elements 5, 6 of one pair engage each other. This movement of points 7 of pin-shaped elements 5 and 6 towards each other can be used for joining together or clamping together the walls of the hollow structures for the purpose of making the anastomosis, as will be explained in more detail hereafter.

Since the joining means in the form of pin-shaped elements 5, 6 comprising points 7 are automatically activated upon expansion of annular element 1 from the first starting diameter to the second, larger joining diameter, it is possible to use a very simple applicator, which consists of a shank-like element for insertion and manipulation, at the distal end of which a head is present, whose diameter can be enlarged. The head may therefore consist of an inflatable balloon, as is known from balloon catheters, or of a mechanically expandable head or the like.

In this embodiment, the following method is used for making an anastomosis.

In the case of a side-to-side anastomosis, incisions are made in the vessel to be bypassed and in the bypass at opposite locations. The applicator is inserted through the open free end of the bypass and passed through the incisions, possibly by means of a guide wire. Annular element 1 is thereby positioned so that one end of annular element 1 is positioned in one vessel and the other end of annular element is positioned in the other vessel, so that pin-shaped elements 5 and 6 are positioned on either side of the walls of the adjacent vessels. When expansion of the applicator causes annular element 1 to expand from the first starting diameter to the second, larger joining diameter, annular element 1 is radially enlarged on the one hand and axially shortened on the other end, wherein the pin-shaped elements 5 and 6 move together, eventually clamping down the walls of the vessels round the incisions, with points 7 becoming fixed in the walls of the vessels. The passage between the two vessels is determined by the diameter of

annular element 1, so that said element functions both to keep the walls of the two vessels together and to keep the passage open. When annular element 1 has reached its joining position, the head of the applicator is reduced to a smaller diameter again and the applicator is withdrawn from the bypass lumen, after which the open end of the bypass is closed.

Figs. 7 - 12 show a second embodiment of the device for making an anastomosis by mechanical means, wherein annular element 1 is a single, sinusoidal, elongated element 8, which expands in circumferential direction. Just like the elongated elements 2 and 3 of the first embodiment, the sinusoidal, elongated element 8 according to this second embodiment has a length dimension which is greater than the circumferential dimension of the annular element in the starting position thereof, and said length dimension of element 8 is at least equal to the circumferential dimension of the annular element in the joining position.

The sine shape of elongated element 8 is such that a number of vertices 9 is positioned centrally in annular element 1, seen in axial view, on which vertices 9 pin-shaped elements 10 and 11 are formed, with two pin-shaped elements 10, 11, which form a pair, being spaced apart at their free ends, seen in axial view, and meeting on elongated element 8 at their bottom ends. Pin-shaped elements 10 and 11 may be provided with a point or other projection 12 at their free ends, on facing sides, so as to be fixed in a vessel wall.

When said annular element 1 according to Figs. 7 - 12 is expanded from the first starting diameter to the second, larger diameter, the ends of the pin-shaped elements 10, 11 of a pair are not automatically moved together, so that it will be necessary to use an applicator which is capable of closing the pin-shaped elements 10, 11 prior to, simultaneously with or after the expansion of annular element 1 so as to clamp down the walls of the adjacent vessels therebetween for making the anastomosis.

Figs. 13 - 15 show an embodiment of an applicator which can be used for that purpose. The applicator is provided with a preferably rigid, shank-like element 13, on the proximal end of which means are provided for
5 manipulating the applicator, such as a grip, and on the distal end of which a head 14 is formed. Head 14 is provided with two axially spaced-apart hubs 15, 16, one of which, for example hub 16, is capable of axial movement, which movement is controlled from the proximal end of shank-like element
10 13. Rigid arms 17 are arranged on hubs 15 and 16 in a star-like fashion, wherein pairs of associated arms 17 of the two hubs 15 and 16 present at corresponding circumferential positions are pivotally interconnected in a point some distance away from their free ends. Arms 17 are also
15 pivotally connected to hubs 15 and 16, with the pivots extending tangentially with respect to shank-like element 13. In this manner clips are formed, as it were.

Fig. 14 shows that annular element 1 is placed on the head 14 of the applicator in such a manner that pin-
20 shaped elements 10 and 11 are positioned between the free ends of arms 17, past a pivot 18, as a result of which the arms are pressed outwards from the position shown in Fig. 13 to the position shown in Fig. 15 upon movement of the hub, as a result of which elongated element 8 is straightened to
25 a shape which extends more in circumferential direction, thereby enlarging the diameter, whilst the reduction of the angle between arms 17 of a pair of arms results in a reduced angle between pin-shaped elements 10 and 11, and the free ends of pin-shaped elements 10 and 11 are moved together,
30 eventually clamping the two walls of the adjacent vessels between them. The placement and removal of the applicator is carried out in a manner which is comparable with the method described with reference to Figs. 1 - 6.

Figs. 16 - 21 show a third embodiment of the device
35 according to the invention, which can be used for intraluminal placement in the case of a side-to-side

anastomosis, but in particular also for extraluminal placement in the case of an end-to-side anastomosis.

In this case, annular element 1 consists of a circular, elongated element 19, which is circumferentially provided in a number of places with pin-shaped elements 10, which axially project to one side from said elongated element 19. The pins may be provided with points 21 thereby, whilst the pin-shaped elements 20 may be flat, or possibly round or the like. As is shown in Figs. 19 - 21, the pin-shaped elements 20 are in large measure bent radially outwards in the joining position of the device, but they may also be bent tangentially.

In order to be able to deform the pin-shaped elements 20 from the starting position to the joining position, the applicator according to Figs. 22 - 24 is provided. Also this applicator is provided with a shank-like element 13 and a head 14, but in this embodiment said head is provided with a detainer 23 in the form of a sleeve to be positioned proximally with respect to annular element 1, which is attached to the head, and with deflector elements 24, which can be moved at least axially, but preferably axially as well as radially, which deflector elements can be manipulated from the proximal end of shank-like element 13. Said deflector elements 24 consist of a fixed hub 25, an axially movable hub 26 and arms 27 which are pivoted together and to hubs 25, 26, which arms can be brought into engagement with the pin-shaped elements 20, and which can be deflected from an axial position to a radial position, wherein annular element 1 is stopped by detainer 23.

When the device according to Figs. 16 - 21 and the applicator according to Figs. 22 - 24 are used for making a side-to-side anastomosis, annular element 1 is placed intraluminally, and the pin-shaped elements 20 are passed through the vessel walls in places surrounding the openings that have been formed by incisions. When the pin-shaped elements 20 are subsequently bent radially outwards, it is no longer possible to remove annular element 1, because

elongated element 19 is positioned inwardly of the wall of one vessel and the radially projecting pin-shaped elements 20 are positioned inwardly of the wall of the other vessel.

In the case of an end-to-side anastomosis, the annular element 1 is slid over the bypass. The bypass is everted round annular element 1 and the pin-shaped elements are passed through the wall of the bypass and through the wall of the vessel to be anastomosed (for example the aorta). Pin-shaped elements 20 can be deflected by extension of the deflector elements 24 of the applicator, and the walls will be fixed with respect to each other.

Figs. 25 - 27 show a variant of the applicator according to Figs. 13 - 15 which is suitable for placing an annular element 1 of a device of the type as shown in Figs. 1 - 6 (shown at the bottom of Figs. 25 and 27) or in Figs. 7 - 12 (shown at the top of Figs. 25 and 27). Also in this embodiment, a head 14 is attached to the shank 13 of the applicator. Said head 14 possesses a blunt end part 28 in this embodiment, which is fixed to shank 13 and also to a housing 29. The fixed connection between shank 13 and housing 29 is schematically illustrated by means of pin 30. A number of slots, eight in the illustrated embodiment, are circumferentially provided, in regularly spaced-apart relationship, in end part 28 and in housing 29. Said slots 31 are wide enough for receiving wedges 32, whereby it is important that slots 31 in end part 28 have the same angle of inclination as the distal front face 33 of wedges 32. Wedges 32 are radially held together by an elastic annular band 34. A control element 35 in the shape of a hollow shaft which can be slid over shank 13 comprises a bevelled front face 36 at the distal end, which is capable of cooperation with a complementary bevel 36' on the proximal end of wedges 32. The angle of inclination of bevel 36' and the front face 36 is smaller than that of the distal front face 33 of wedges 32.

An annular element 1 positioned in the applicator can be expanded from the starting position to the joining

position by pressing wedges 32 outwards. This can be effected by moving control element 35 distally forwards, which control element presses wedges 32 outwards, via bevels 36', with its inclined front face 36, whereby the direction of the movement of wedges 32 corresponds with the direction of front faces 33 and the cooperating surfaces of end part 28. The combined axial and radial movement of wedges 32 causes the annular element surrounding wedges 32 both to expand radially and to be clamped together between the adjacent housing surface and the wedge surface, as a result of which pin-shaped elements 5, 6 and 10, 11 respectively of annular element 1 are moved together, clamping the vessel walls down between them. When control element 35 moves back, the elastic band 34 causes wedges 32 to return to the starting position. Thus, the applicator can be withdrawn from annular element 1 and be removed in a simple and reliable manner.

Figs. 28 - 30 show a variant of the applicator according to Figs. 22 - 24, which can be used in combination with an annular element 1 of the type according to Figs. 16 - 21. The head 14 of this variant comprises a hollow shaft 37, with a blunt end part 38 present at the distal end thereof. Rectangular openings 39 (eight, for example) are provided in regularly spaced-apart relationship in the circumference of hollow shaft 37. Said hollow shaft 37 can move axially with respect to a housing 40, whose distal end surface 41 can serve as an anvil for annular element 1. Wedges 42 are placed in openings 39, which wedges are pivoted to the hollow shaft by means of resiliently flexible plates 43, in such a manner that wedges 42 can move outwards about a substantially tangential axis, from their starting position (Fig. 28) in openings 39 to a joining position (Fig. 30) in the direction of housing 40. Said movement is effected by moving a control element 44 in the form of a bar comprising a bevelled point 45 in forward direction, as a result of which the wedges are tilted outwards through 90°, in which joining position they are locked by the

circumference of said control element 44. When housing 40 is moved axially forward with respect to hollow shaft 37, in the direction of wedges 42, the pin-shaped elements 20 of annular element 1 will come into contact with the wedges 42, and the pin-shaped elements 20 will be deflected outwards in a desired manner by the specially formed cavities 46 present in said wedges so as to fix annular element 1 of the device to the vessel walls. Wedges 42 will return to the starting position when control element 44 is withdrawn, and the applicator can be removed. In principle it would also be possible to effect direct deflection of pin-shaped elements 20 through expansion of wedges 42.

Figs. 31 - 36 show another variant of an applicator, which can for example be used for inserting the device according to Figs. 1 - 6 or 7 - 12. The applicator is therefore arranged for effecting a radial expansion of annular element 1 of the device and subsequently clamping together the joining means, such as pin-shaped elements 5, 6 or 10, 11, in axial direction or deforming them in some other manner. The difference with the preceding embodiments of the applicator is the fact that the embodiment according to Figs. 31 - 36 is arranged for effecting the radial and axial deformations of the device in two separate steps. First the annular element 1 is radially expanded, and then the joining means are moved to their joining position. The advantage of this embodiment is the fact that the joining means are prevented from closing prematurely and thus missing part of the vessel wall.

In Figs. 31 - 36, shank-like element 13, head 14 and detainer 23 can be distinguished. An end portion 47 having a convex end surface is formed on the distal end of shank-like element 13, whilst end part 47 is wedge-shaped or conical on proximal side 48. Besides shank-like element 13 and detainer 23, a third, relatively movable part 49 is provided, which can be moved both with respect to shank-like element 13 and with respect to detainer 23 from a control position outside the body. Part 49 and/or detainer 23 are

circumferentially provided with a number of radially extending slots 50 for movably accommodating, at least in part, an equal number of arms 51. Arms 51 can move between the innermost starting position, in which they abut against a conical surface 52 of movable part 49, and an outermost joining position, in which they abut against the inner wall of detainer 23 (Figs. 32, 33). Arms 51 comprise an outwardly curved deflection surface 53 near their distal ends, which is to mate with pin-shaped elements of annular element 1, which may be provided round arms 51, adjacently to deflection surfaces 53. An elastic band 54 (see Figs. 35, 36) may extend through radial notches 55 present near the distal ends of arms 51, which band functions to cause arms 51 to spring back to an inward position.

As is shown in Fig. 34, it is also possible to use arms which are interconnected by an annular part 56 at their proximal ends instead of separate arms 51. This one-piece assembly may for example be in the form of a plastic moulding, whereby the pivoting movement of arms 51 is made possible by the elastic properties of the relatively long arms. Slots 50 are no longer required in this manner, since annular part 56 holds arms 51 in position.

The operation of the applicator is as follows. In the position as shown in Fig. 31, the applicator and the annular element 1 of the device, which is present thereon (not shown), are moved to their destination, and then the shank-like element 13 and the end part 47 are withdrawn in proximal direction with respect to part 49 (or part 49 is extended), and arms 51 are pressed radially outwards by the mating cooperation between the wedge-shaped proximal side 48 of end part 47 and the associated wedge-shaped surfaces of arms, because arms 51 are supported against a shoulder of part 49 (see Fig. 32). Annular element 1 is thereby deformed radially outwards by arms 51 to a larger diameter. Detainer 23 is then moved relative to shank-like element 13 and part 49, as a result of which the end face of detainer 23 is moved in the direction of the deflection surfaces and the

joining means are deformed in such a manner that the vessel walls of the hollow structures are interconnected. When shank-like element 13 and part 49 are moved apart again, elastic band 54 will return arms 51 to their starting position as shown in Fig. 31.

With the applicator according to Figs. 37 - 40, the isovolumetric behaviour of some elastic and readily deformable material, such as rubber, is utilized for the radial expansion of annular element 1 of the device. The axial compression of the material will result in axial contraction and, if inward deformation is not possible, to radially outward expansion. In the illustrated embodiment, an isovolumetric core 57 is provided, on which annular element 1 of the device can be placed. Head 14 of said applicator furthermore comprises a sleeve 58 which is axially movable with respect to shank-like element 13, which sleeve comprises an end part 59 capable of cooperation with an end part 60 of shank-like element 13. Pivoted radial supports 61 are connected to the associated end parts 59, 60, they support circumferentially provided plates 62, which are held together by an associated elastic band 63, which also provides the return force. By moving the end parts 59, 60 together, the plates 62 are moved from the original sloping position as shown in Figs. 38, 40 to an eventual joining position as shown in Figs. 37, 39, wherein said plates extend practically perpendicularly to shank-like element 13. The facing surfaces of plates 62 are then capable of deforming the joining means upon further movement of end parts 59, 60 towards each other when the isovolumetric core 57 is compressed and the annular element is expanded thereby and, as already mentioned before, the joining means are moved to their joining position. This embodiment of the applicator is suitable for drastic miniaturisation.

Fig. 41 shows the result of a side-to-side anastomosis of two hollow structures, such as blood vessels, wherein loose staples 64 are used as joining means for the

vessel walls. One of the above-described applicators may be used, providing that means are used for holding the staples 64 correctly spaced apart when said staples 64 are being inserted and moved to their joining position. Also in this
5 embodiment the staples are placed intraluminally, whilst a guide wire may be used for moving the applicator to its correct position.

From the above it will have become apparent that the invention provides a system for making anastomoses
10 between hollow structures by mechanical means, by means of which system an anastomosis can be made in a quick and reliable manner, as a result of which the negative effects of an anastomosis for the patient are minimized and the system is suitable for a large number of applications.

15 The invention is not limited to the above-described embodiments as shown in the drawing, which can be varied in several ways within the scope of the invention. Thus, the expandable version of the device might also be made of a resilient material or of a shape-memorizing metal, so that
20 the device can move to the expanded position without external forces being exerted when the device is being provided. The elongated elements may not be recognizable as such, but they may be encountered in a different type of structure.

CLAIMS

1. A system for making anastomoses between hollow structures by mechanical means, characterized by a device in the shape of an annular or tubular element comprising circumferentially provided means for joining the abutting
5 walls of the hollow structures together, as well as an applicator for moving said annular or tubular element in position and activating the joining means thereof.

2. A device for use in the system for making anastomoses between hollow structures by mechanical means
10 according to claim 1, characterized by an annular or tubular element comprising joining means provided circumferentially thereon for joining the abutting walls of the hollow structures together.

3. A device according to claim 2, wherein said
15 joining means comprise a number of pin-shaped elements which are circumferentially provided on said annular element, which pin-shaped elements can be moved or deformed between a starting position and a joining position.

4. A device according to claim 3, which is intended
20 for intraluminal side-to-side anastomosis, wherein respectively two pin-shaped elements are provided at the same position, seen in circumferential direction, wherein at least the free ends of two associated pin-shaped elements are spaced apart in the starting position, seen in axial
25 direction, whilst they have been moved together in the joining position.

5. A device according to any one of the preceding claims, which is intended for intraluminal placement, wherein said annular element can be permanently deformed
30 from a first diameter in the starting position to a second, larger diameter in the joining position.

6. A device according to claim 5, wherein said annular element is made up of at least one elongated element having a length dimension which is greater than the
35 circumferential dimension of said annular element in the

first diameter and which is at least equal to the circumferential dimension of said annular element in the second diameter, which element extends along a line which deviates from a contour line in the first diameter and which
5 can be straightened so as to extend along a line which resembles the contour line more closely.

7. A device according to claim 6, wherein said elongated element extends sinusoidally or in a different, zigzag-like fashion.

10 8. A device according to claims 5 and 7, wherein two zigzag-like elements are arranged side by side in axial direction, which elements are interconnected near their vertices facing each other, and wherein the pin-shaped elements are fixed to the vertices that face away from each
15 other.

9. A device according to claim 3, which is intended for making an intraluminal side-to-side anastomosis or an end-to-side anastomosis, wherein the pin-shaped elements extend at least substantially axially in the starting
20 position and wherein said pin-shaped elements can be bent to the joining position deviating from the axial position, for example a substantially radial or tangential position or the like, so as to make a joint.

10. An applicator for use in the system according
25 to claim 1, which is intended for placing the device according to any one of the claims 2 - 9, which applicator is provided with means for positioning said annular or tubular element and activating the joining means thereof.

11. An applicator according to claim 10, which is
30 intended for placing the device according to claim 3, which applicator is provided with a, preferably rigid, shank-like element and with a head, which head can be adjusted in such a manner that the pin-shaped elements of the device are moved or deformed from the starting position to the joining
35 position when said adjusting takes place.

12. An applicator according to claim 11, which is intended for placing the device according to claim 4,

wherein said head is provided with means for moving associated pin-shaped elements towards each other.

13. An applicator according to claim 11 or 12, which is intended for placing the device according to any one of the claims 5 - 8, wherein the head of the applicator can also expand in radial direction from a first diameter to a second diameter.

14. An applicator according to claim 13, wherein said head is provided with two axially spaced-apart hubs comprising arms arranged in a star-like fashion thereon, which hubs are movable in axial direction with respect to each other, wherein the arms of the two hubs are pivotally interconnected at a point some distance away from their free ends so as to form clamps.

15. 15. An applicator according to claim 13, wherein said head is circumferentially provided with a number of equally spaced elements, such as wedges, around which the device can be placed, and which can be moved axially and radially outwards by means of a control element, whereby the device is expanded in radial direction and contracted in axial direction.

16. An applicator according to claim 13, wherein said head is provided with an isovolumetrically deformable element, for example of rubber, on which the annular or tubular element of the device can be placed, and which can be axially contracted and be outwardly expanded so as to cause the device to expand in radially outward direction.

17. An applicator according to claim 16, wherein said head is provided with two axially spaced-apart hubs, which are axially movable with respect to each other, with a number of outwardly pivotable elements, which are equally spaced over the circumference, as well as the isovolumetric element, which is positioned inwardly thereof, present therebetween.

18. An applicator according to claim 11, which is intended for placing the device according to claim 9, which applicator comprises a shank-like element and a head, which

is fitted with a detainer for stopping the device in axial direction, and axially movable deflector means for deflecting the pin-shaped elements.

19. An applicator according to claim 18, wherein
5 said detainer is a hollow shaft or ring, and wherein said axially movable deflector means are provided with two axially spaced-apart hubs which are axially movable with respect to each other and to the detainer, on which hubs arms are arranged in a star-like fashion, wherein the arms
10 of the two hubs are pivotally interconnected.

20. An applicator according to claim 18, wherein said detainer is a hollow shaft or ring, and wherein said axially movable deflector means are provided with a number of circumferentially provided, substantially radially
15 disposed wedges on the hub, which are each capable of pivoting movement about a substantially tangential axis in the direction of said detainer.

21. An applicator for use in the system for making anastomoses between hollow structures by mechanical means
20 according to claim 1, characterized by a shank-like element and by a head for supporting and activating the joining means provided thereon, in such a manner that said joining means are moved or deformed from the starting position to the joining position upon activation as a result of
25 expansion of the head in radial direction from a first diameter to a second diameter and of axial contraction in two separate steps.

22. An applicator according to claim 21, wherein said head is provided with first, second and third parts
30 which are capable of axial movement relative to each other, wherein relative movement of said first and said second parts causes the joining means to move in radial direction and wherein relative movement of said first and said third parts causes the joining means to contract in axial
35 direction.

23. An applicator according to claim 21, wherein said head is circumferentially provided with a number of

equally spaced elements, such as wedges, around which the device can be placed, which elements can be moved axially and radially outwards by means of a control element, whereby the device is expanded in radial direction and contracted in
5 axial direction.

24. A method for making intraluminal side-to-side or side-to-end anastomoses between hollow structures by mechanical means, characterized by providing of an applicator and associated joining means for joining the
10 abutting walls of the hollow structures together, placing said joining means round the applicator, inserting said applicator and said joining means into one of said hollow structures to a location internally of the abutting walls of the hollow structures, and activating said applicator, and
15 thus the passing of said joining means through said abutting walls or the clamping of said joining means against said abutting walls for the purpose of keeping said abutting walls in sealing contact with each other.

25. A method according to claim 24, wherein joining
20 means are used which are formed on a single annular or tubular element.

26. A method according to claim 24, wherein a number of loose staples are used as the joining means.

1/12

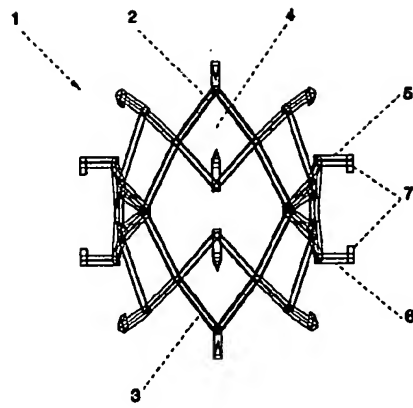


Fig. 1

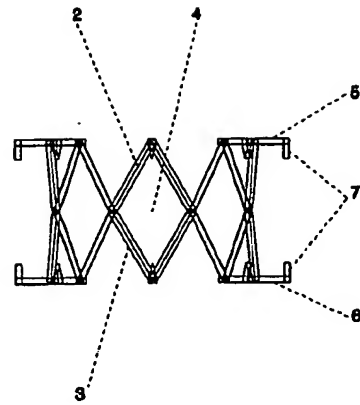


Fig. 2

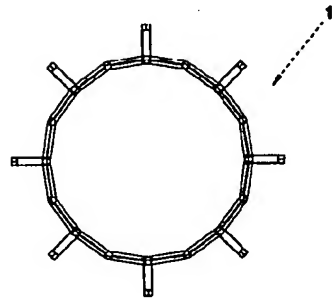


Fig. 3

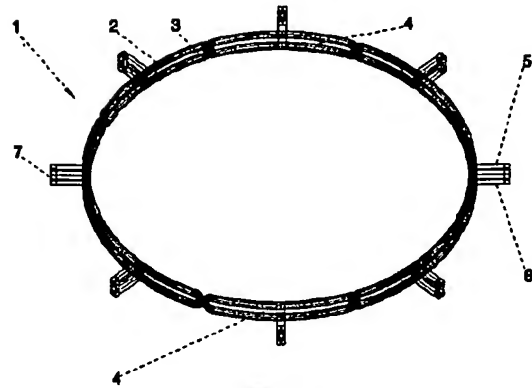


Fig. 4

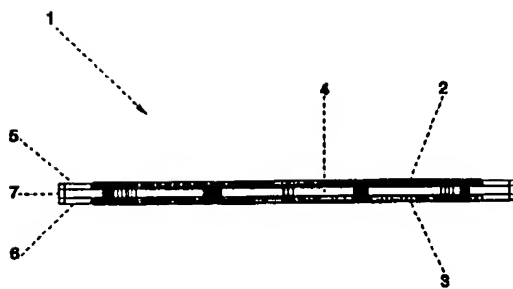


Fig. 5

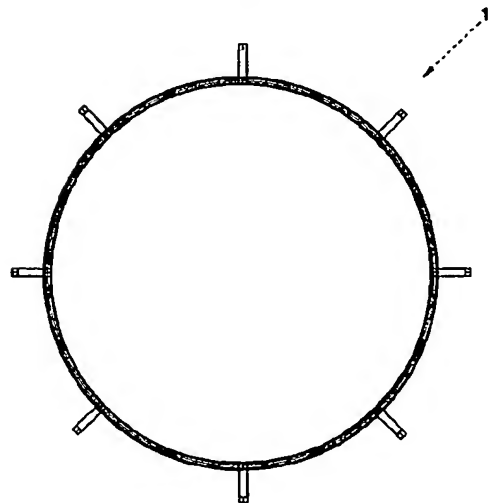


Fig. 6

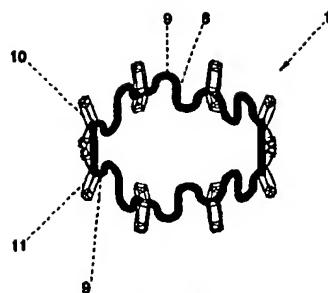


Fig. 7

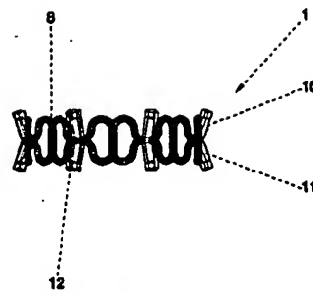


Fig. 8

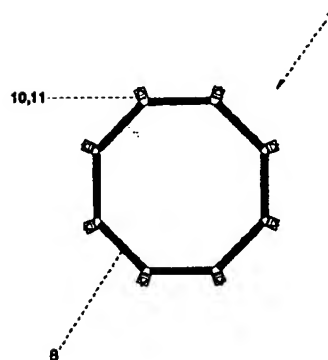


Fig. 9

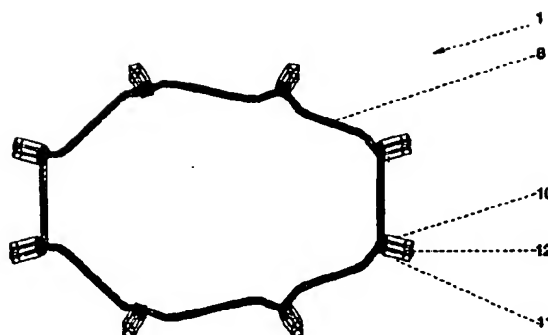


Fig. 10

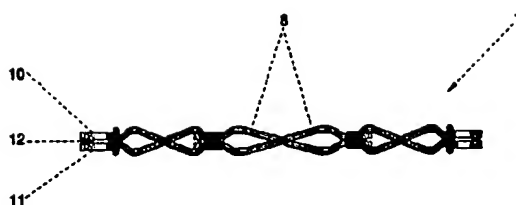


Fig. 11

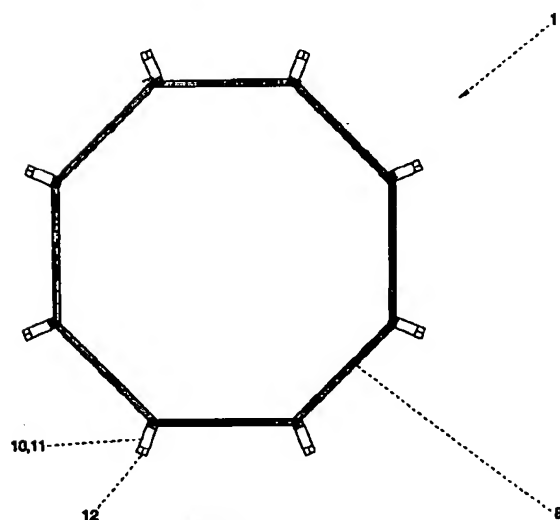


Fig. 12

3/12

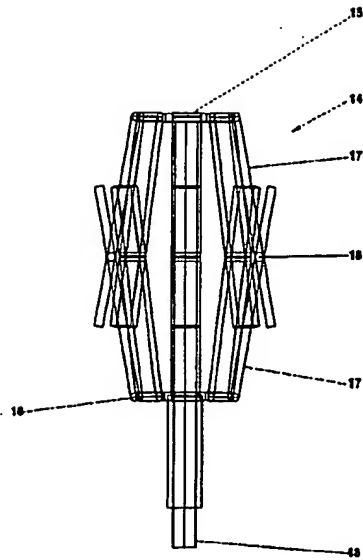


Fig. 13

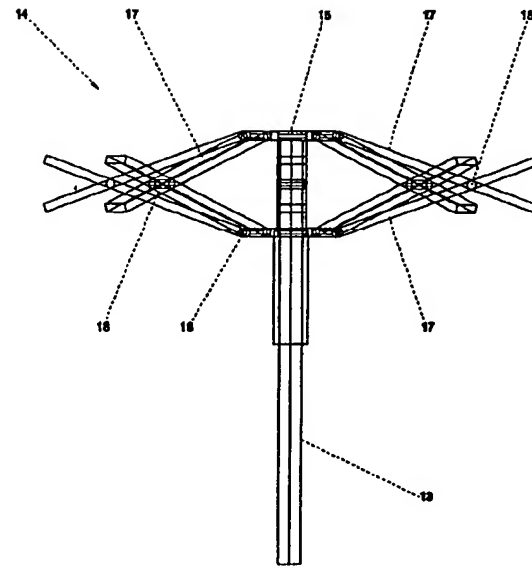


Fig. 15

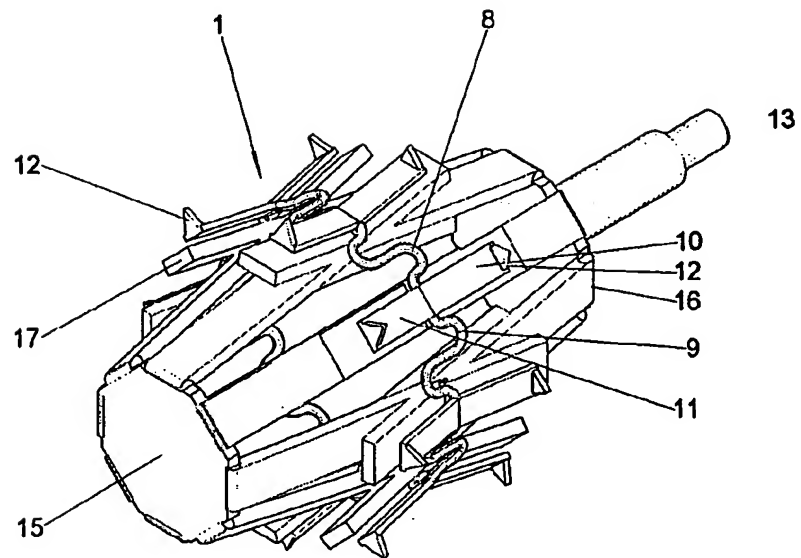


Fig. 14

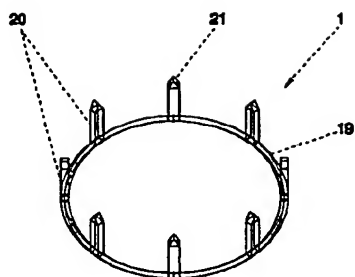


Fig. 16

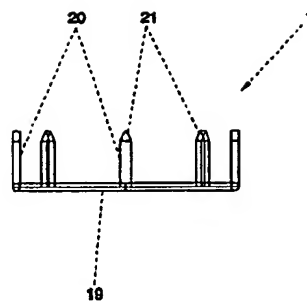


Fig. 17

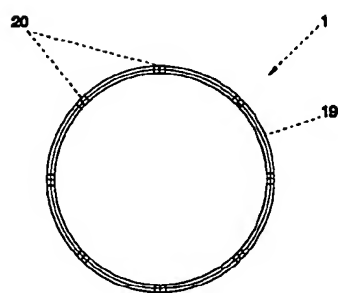


Fig. 18

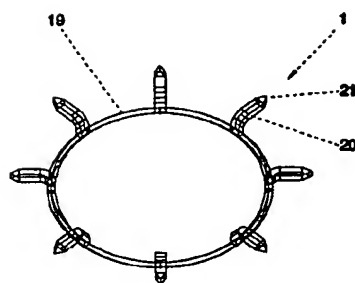


Fig. 19

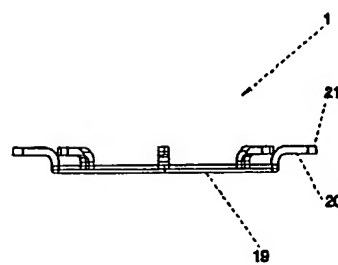


Fig. 20

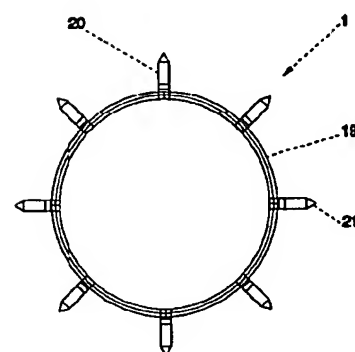


Fig. 21

5/12

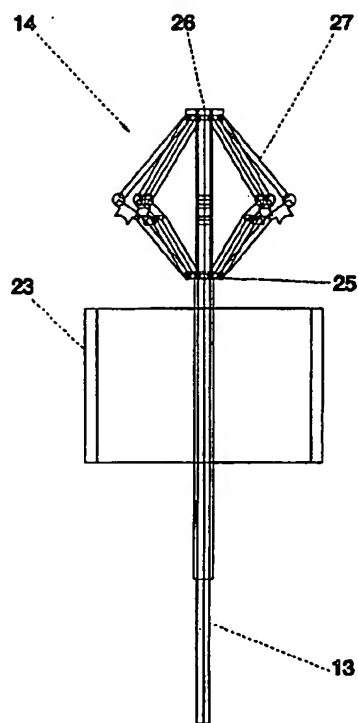


Fig. 22

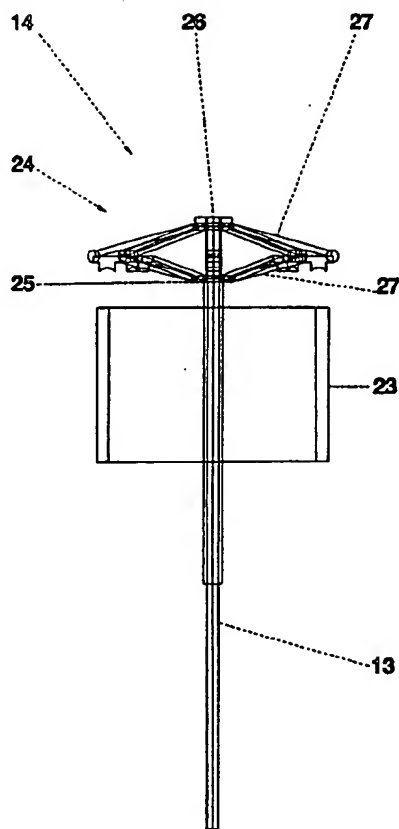


Fig. 24

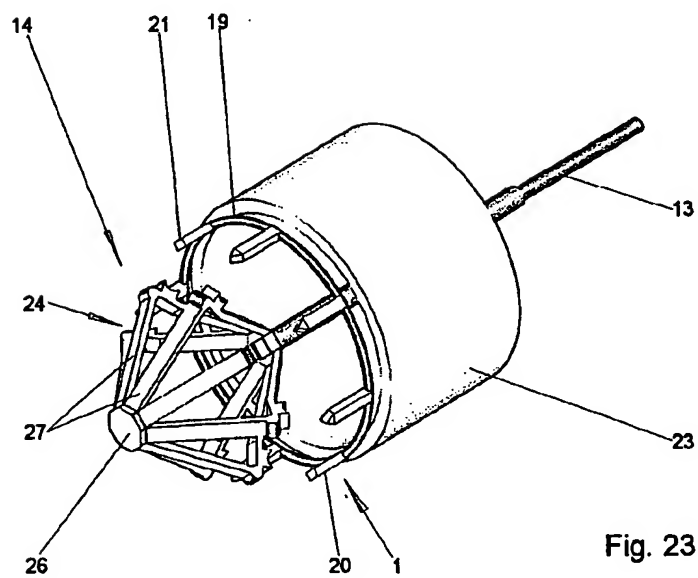


Fig. 23

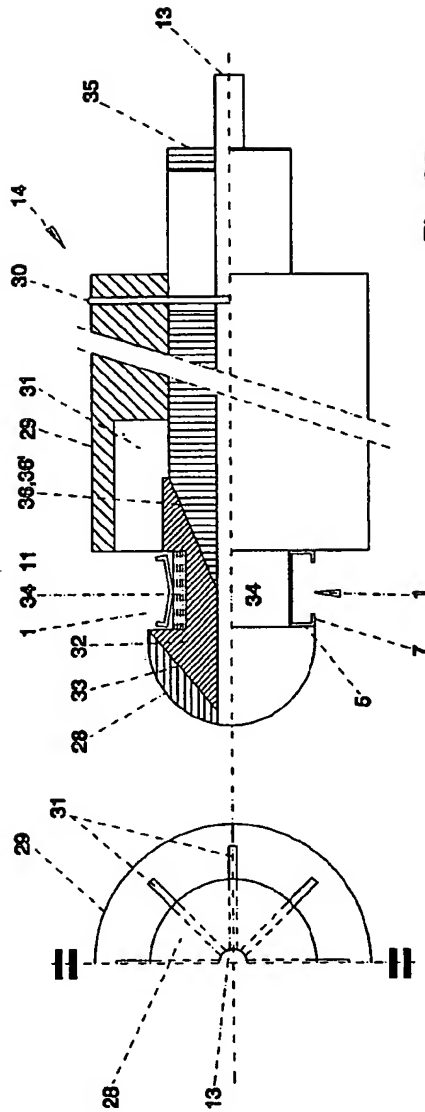


Fig. 25

Fig. 26

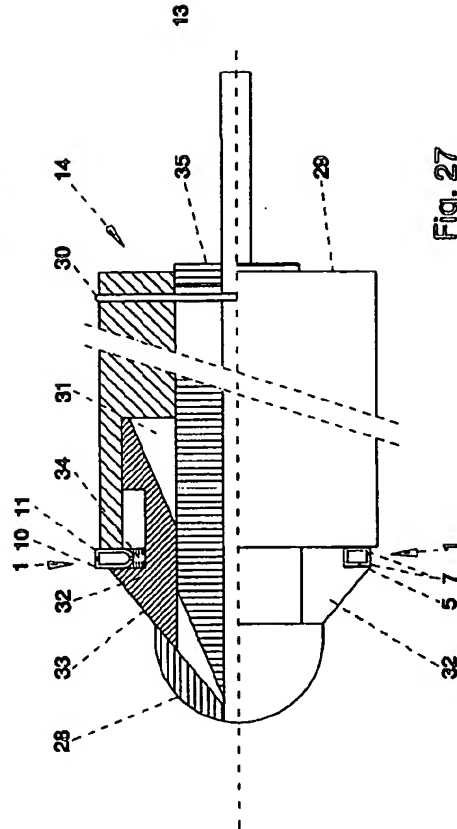


Fig. 27

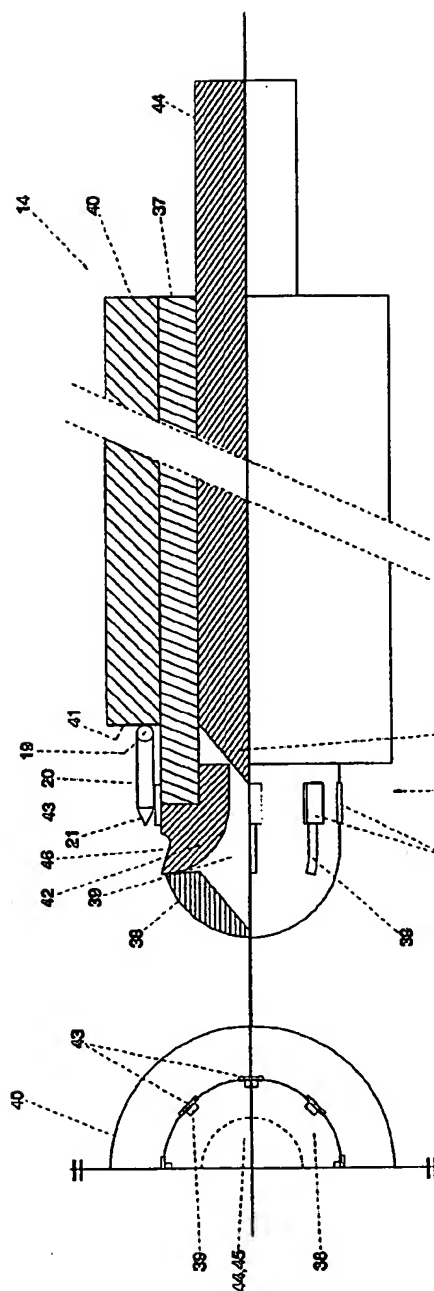


Fig. 29

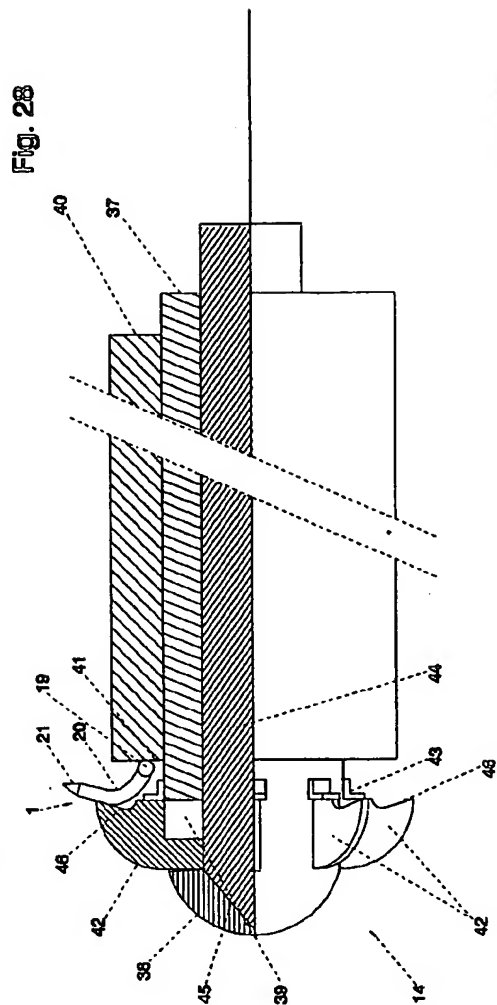


Fig. 28

Fig. 30

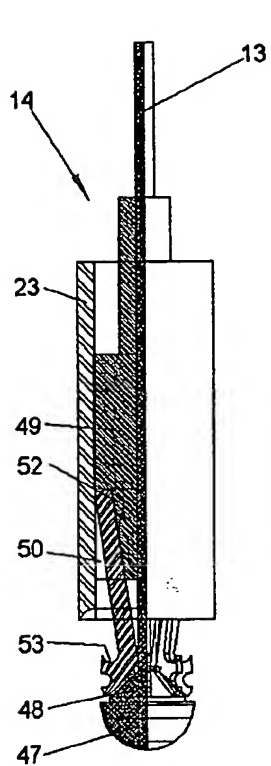


Fig. 31

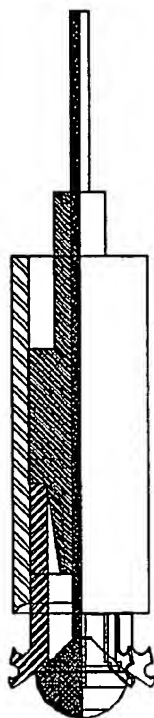


Fig. 32

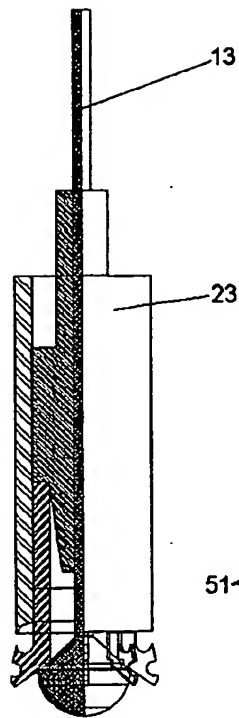


Fig. 33

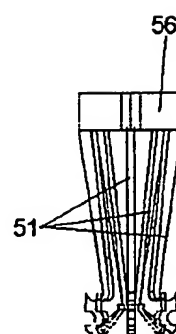


Fig. 34

9/12

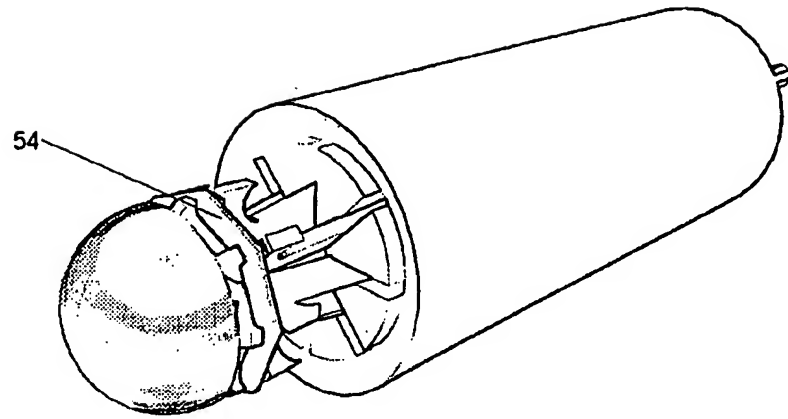


Fig. 35

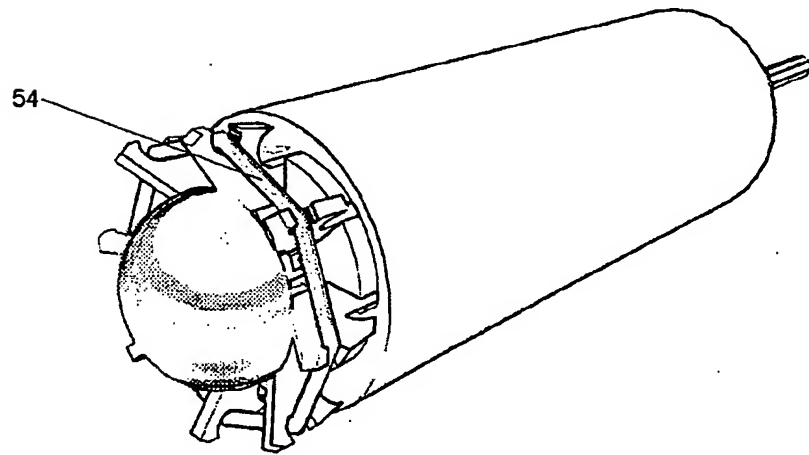


Fig. 36

10/12

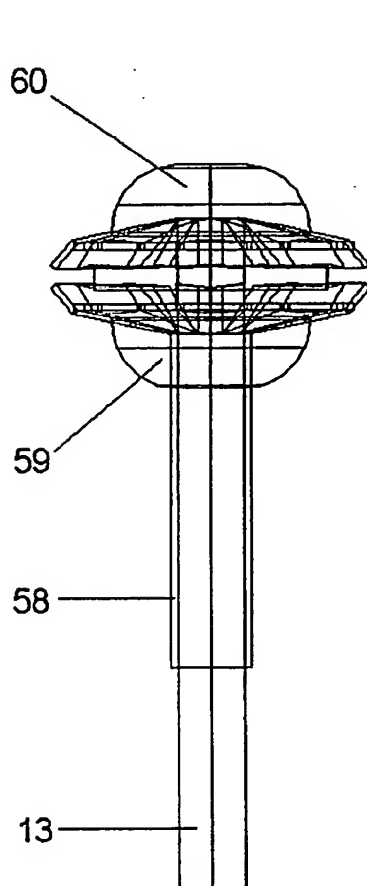


Fig. 37

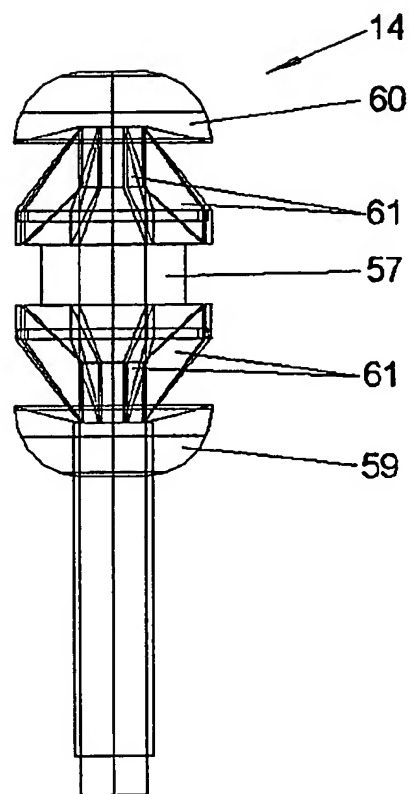


Fig. 38

11/12

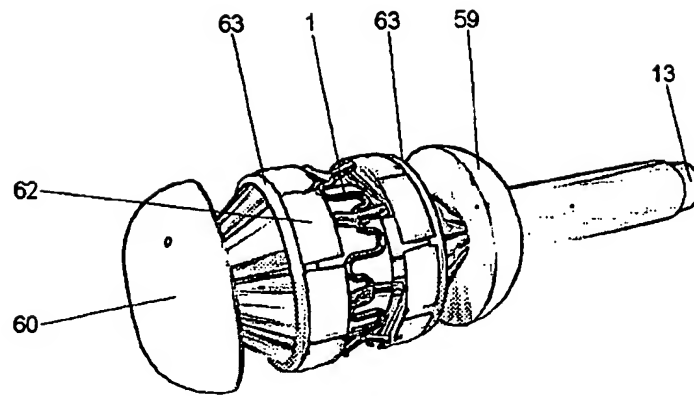


Fig. 40

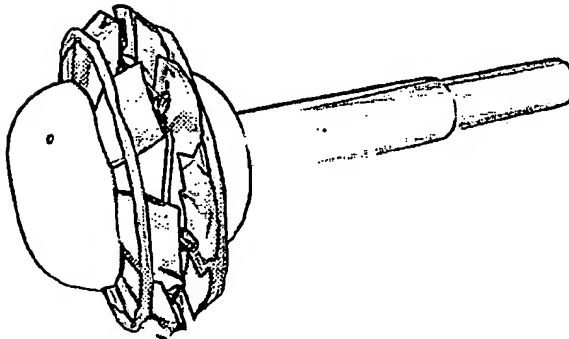


Fig. 39

12/12

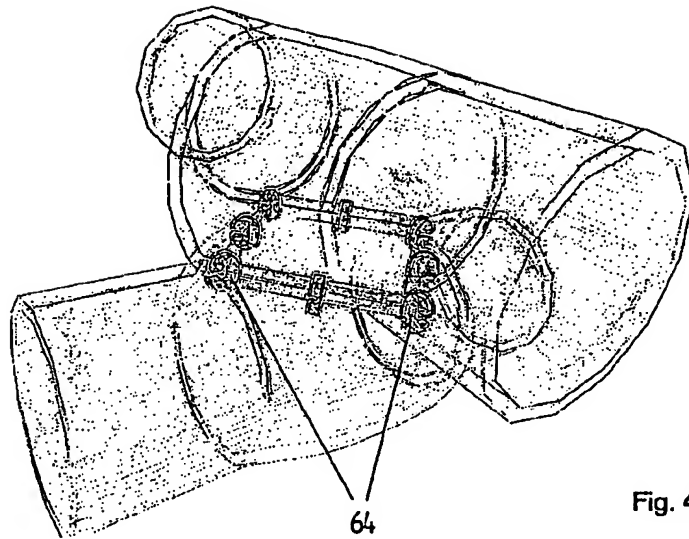


Fig. 41

INTERNATIONAL SEARCH REPORT

International Application No
PCT/NL 98/00605

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/115 A61B17/064 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 872 874 A (TAHERI) 10 October 1989 see figures 8-12	1-4, 10, 11, 13
X	US 5 035 702 A (TAHERI) 30 July 1991 see figures 8, 14-19	1-4, 9-12
X	US 5 234 447 A (KASTER) 10 August 1993 see figures 1-5, 10, 14-19	1-4, 9-12, 18 20
X	US 4 681 110 A (WIKTOR) 21 July 1987 see figures 1, 2, 4, 5	1-3, 5-7, 10
X	US 3 657 744 A (ERSEK) 25 April 1972 see column 3, line 1-6; figure 1	1, 2, 5-7, 10, 13
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

25 January 1999

Date of making of the international search report

1. 03. 99

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 eponl,
Fax: (+31-70) 340-3016

Authorized officer

BARTON, S

INTERNATIONAL SEARCH REPORT

International Application No

PCT/NL 98/00605

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 539 237 A (COOK) 28 April 1993 see column 8; figure 15 ---	1-3,5-8, 10
X	US 4 214 587 A (SAKURA) 29 July 1980 see figures 1,3,6-9 ---	1-3,5-7, 10
X	US 4 368 736 A (KASTER) 18 January 1983 see figures 1,4 ---	1-3,10
A	DE 28 22 603 A (THIERFELDER) 29 November 1979 see figures 7-12 ---	14,19
A	US 5 562 690 A (GREEN) 8 October 1996 see figure 13 ---	19
A	WO 89 08433 A (LAZARUS) 21 September 1989 -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NL 98/ 00605

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 24-26
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

1. Claims: 1;2-9;10-15,18-20

Anastomosis system with inter alia special expansion/clamping mechanisms.

2. Claims: 10,11,13,16,17

Anastomosis system with isovolumetric expander.

3. Claims: 10,21-23

Anastomosis system with separated radial expanding and axial contracting functions.

INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No

PCT/NL 98/00605

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4872874 A	10-10-1989	NONE	
US 5035702 A	30-07-1991	NONE	
US 5234447 A	10-08-1993	WO 9504503 A	16-02-1995
		AU 4803593 A	28-02-1995
		EP 0713373 A	29-05-1995
		US 5403333 A	04-04-1995
		US 5366462 A	22-11-1994
US 4681110 A	21-07-1987	NONE	
US 3657744 A	25-04-1972	NONE	
EP 539237 A	28-04-1993	US 5387235 A	07-02-1995
		AU 669338 B	06-06-1996
		AU 2735392 A	13-05-1993
		CA 2081424 A	26-04-1993
		US 5456713 A	10-10-1995
		US 5562726 A	08-10-1996
		US 5693084 A	02-12-1997
		US 5720776 A	24-02-1998
		US 5755777 A	26-05-1995
		JP 5305092 A	19-11-1993
US 4214587 A	29-07-1980	NONE	
US 4368736 A	18-01-1983	NONE	
DE 2822603 A	29-11-1979	NONE	
US 5562690 A	08-10-1996	NONE	
WO 8908433 A	21-09-1989	US 5104399 A	14-04-1992
		AT 137655 T	15-05-1996
		AU 637318 B	27-05-1993
		AU 3439289 A	05-10-1989
		AU 663583 B	12-10-1995
		AU 3826193 A	01-07-1993
		AU 693294 B	25-06-1998
		AU 4088696 A	04-04-1996
		AU 8706698 A	14-01-1999
		CA 1335528 A	16-05-1995
		DE 68926452 D	13-06-1996
		DE 68926452 T	12-09-1996
		EP 0407425 A	16-01-1991
		EP 0688544 A	27-12-1995
		JP 2771001 B	02-07-1998
		JP 3503246 T	25-07-1991
		US 5397345 A	14-03-1995
		US 5662700 A	02-09-1997
		US 5693083 A	02-12-1997
		US 5669936 A	23-09-1997
		US 5562728 A	08-10-1996
		US 5275622 A	04-01-1994
		US 5749920 A	12-05-1998